

AMENDMENTS TO THE CLAIMS

Please replace all prior versions of listings of the claims with the following listing of the claims

Listing of the Claims:

1. (Withdrawn) A pharmaceutical composition for transdermal delivery comprising:
at least one skin permeation enhancer; and

at least one active ingredient or pharmaceutically acceptable salt thereof,
wherein the composition is for transdermal delivery of the active ingredient.

2. (Withdrawn) The composition of claim 1 wherein the skin permeation enhancer is present in an amount from about 0.1% by weight to about 20% by weight based on the total weight of the composition .

3. (Withdrawn) The composition of claim 2 wherein the active ingredient is present in an amount from about 0.1% by weight to about 30% by weight based on the total weight of the composition .

4. (Withdrawn) The composition of claim 3 wherein the skin permeation enhancer and active ingredient are present in a weight ratio from about 3.0:0.5 to about 0.5:3.0 based upon the total weight of the composition.

5. (Withdrawn) The composition of claim 4 further comprising at least one effervescent agent wherein the effervescent agent is present in an amount from about 10% to about 90% by weight based on the total weight of the composition.

6. (Withdrawn) The composition of claim 2 wherein the skin permeation enhancer comprises isopropyl myristate, cetyl palmitate, clarified sesame oil, borage, evening primrose oil, spirulina oil, sunflower oil, safflower oil, flaxseed oil, walnut oil, canola oil, soybean oil, and mixtures thereof.

7. (Withdrawn) The composition of claim 6 wherein the active ingredient comprises aspirin, sodium salicylate, choline magnesium trisalicylate, salsalate, diflunisal, salicylsalicylic acid, sulfasalazine, olsalazine, acetaminophen, indomethacin, sulindac, etodolac, tolmetin, diclofenac, ketorolac, ibuprofen, naproxen, flurbiprofen, ketoprofen, fenoprofen, indoprofen, oxaprozin, mefenamic acid, meclofenamic acid, piroxicam, tenoxicam, meloxicam, lornoxicam, phenylbutazone, oxyphenbutazone, nabumetone, diphenhydramine hydrochloride, clemastine fumarate, brompheniramine maleate, chlorpheniramine maleate, dexchlorpheniramine maleate, triprolidine hydrochloride, promethazine, hydroxyzine hydrochloride, terfenadine, astemizole, azatadine maleate, cyproheptadine hydrochloride, loratadine, carboxamine maleate, diphenylpyraline hydrochloride, phenindamine tartrate, tripeleannamine hydrochloride, methdilazine hydrochloride, trimprazine tartrate, beclomethasone, dipropionate, triamcinolone acetonide, prednisone, Sumatriptan/Imitrex, Imitran, dihydroergotamine, ergotamine tartrate, dolasetron mesilate, dotarizine, flupirtine, tenosal, tolfenamic acid, arotinolol, dihydroergocryptine, cyclosporin, azathioprine, methotrexate, glucocorticoids, penicillamine, hydroxychloroquine, colchicine, allopurinol, probenecid, sulfapyrazone, ginseng, bilberry, black cohosh, cat's claw, cayenne, chamomile, chaste tree, cranberry, echinacea, eleuthero, ephedra, evening primrose oil, feverfew, flax, garlic, ginger, gingko, golden seal, green tea, hawthorn, kava kava, licorice, milk thistle, peppermint, saw palmetto, St. John's wort, methylsulfonyl methane, DMSO, and combinations thereof.

8-12. (Canceled)

13. (Withdrawn) A method of preparing a pharmaceutical composition for transdermal delivery comprising combining at least one skin permeation enhancer with at least one active ingredient or pharmaceutically acceptable salt thereof, at a temperature sufficient to dissolve the active ingredient without decomposing the active ingredient to obtain an enhancer mixture; and wherein preparation of the composition is accomplished at ambient temperature.

14. (Withdrawn) A method of claim 13, wherein the skin permeation enhancer is present in an amount from about 0.1% to about 20% by weight based on the total weight of the composition.

15. (Withdrawn) A method of 14, wherein the active ingredient is present in an amount from about 0.1% to about 30% by weight based on the total weight of the composition.

16. (Withdrawn) A method of claim 15, further comprising at least one effervescent agent wherein the effervescent agent is present in an amount from about 10% to about 90% by weight based on the total weight of the composition.

17. (Withdrawn) The method of claim 16, wherein the composition is prepared in a pharmaceutical formulation comprising tablet, gel, spray, and cream.

18. (Currently Amended) A method of treating and/or alleviating at least one of pain, aches, and inflammation comprising,

dissolving in a bath a pharmaceutical composition for transdermal delivery comprising:

at least one skin permeation enhancer comprising clarified sesame oil;

at least one effervescent agent; and

at least one active ingredient or pharmaceutically acceptable salt thereof comprising ibuprofen; and

[[,]]immersing a body part of a human being to be treated in the bath containing the dissolved pharmaceutical composition.

19. (Currently Amended) The method of claim 18, wherein the composition is a tablet comprising:

the at least one skin permeation enhancer in an amount from about 1% to about 5% by weight based on the total weight of the composition; and

the at least one active ingredient present in an amount from about 1% by weight to about 10% by weight based on the total weight of the composition;

~~wherein the composition further comprises:~~

the at least one effervescent agent present in an amount from about 30% to about 70% by weight based on the total weight of the composition; and

at least one acid agent present in an amount from about 20% to about 40% by weight based on the total weight of the composition;

wherein

~~the skin permeation enhancer comprises isopropyl myristate, clarified sesame oil, and mixtures thereof;~~

~~the effervescent agent is sodium bicarbonate;~~

~~the acid agent is citric acid; and~~

~~the active ingredient is ibuprofen;~~

~~wherein the composition is a tablet; and~~

~~wherein the method is performed at least twice during a 24 hour period.~~

20. (Withdrawn – Currently Amended) The method of claim 18, wherein the composition for transdermal delivery comprises:

the at least one skin permeation enhancer in an amount from about 1% to about 5% by weight based on the total weight of the composition; and

the at least one active ingredient present in an amount from about 1% by weight to about 10% by weight based on the total weight of the composition;

wherein the composition further comprises

the at least one effervescent agent present in an amount from about 30% to about 70% by weight based on the total weight of the composition; and

at least one acid agent in an amount from about 20% to about 40% by weight based on the total weight of the composition; and

wherein

the skin permeation enhancer further comprises isopropyl myristate, cetyl palmitate, clarified sesame oil, borage, evening primrose oil, spirulina oil, sunflower oil, safflower oil, flaxseed oil, walnut oil, canola oil, soybean oil, and or mixtures thereof;

the effervescent agent comprises sodium bicarbonate, potassium bicarbonate, lithium bicarbonate, magnesium bicarbonate, calcium bicarbonate, ammonium bicarbonate, and or mixtures thereof;

the acid agent comprises citric acid, succinic acid, fumaric acid, adipic acid, malic acid, and or mixtures thereof; and

the active ingredient further comprises aspirin, sodium salicylate, choline magnesium trisalicylate, salsalate, diflunisal, salicylsalicylic acid, sulfasalazine, olsalazine, acetaminophen, indomethacin, sulindac, etodolac, tolmetin, diclofenac, ketorolac, ~~ibuprofen~~, naproxen, flurbiprofen, ketoprofen, fenoprofen, indoprofen, oxaprozin, mefenamic acid, meclofenamic acid, piroxicam tenoxicam, meloxicam, lornoxicam, phenylbutazone, oxyphenbutazone, nabumetone, diphenhydramine hydrochloride, clemastine fumarate, brompheniramine maleate, chlorpheniramine maleate, dexchlorpheniramine maleate, triprolidine hydrochloride, promethazine, hydroxyzine hydrochloride, terfenadine, astemizole, azatadine maleate, cyproheptadine hydrochloride, loratadine, carbinoxamine maleate, diphenylpyraline hydrochloride, phenindamine tartrate, tripeleannamine hydrochloride, methdilazine hydrochloride, trimprazine tartrate, beclomethasone, dipropionate, triamcinolone acetonide, prednisone, Sumatriptan/Imitrex, Imigran, dihydroergotamine, ergotamine tartrate, dolasetron mesilate, dotarizine, flupirtine, tenosal, tolfenamic acid, arotinolol, dihydroergocryptine, cyclosporin, azathioprine, methotrexate, glucocorticoids, penicillamine, hydroxychloroquine, colchicine, allopurinol, probenecid, sulfipyrazone, ginseng, bilberry, black cohosh, cat's claw, cayenne, chamomile, chaste tree, cranberry, echinacea, eleuthero, ephedra, evening primrose oil, feverfew, flax, garlic, ginger, gingko, golden seal, green tea, hawthorn, kava kava, licorice, milk thistle, peppermint, saw palmetto, St. John's wort, methylsulfonyl methane, DMSO, and or combinations thereof; and

wherein the composition for transdermal delivery is administered to a human being at least twice during a 24 hour period.

21. (Previously Presented) The method according to claim 18, wherein the immersing a body part comprises soaking the body part for at least 5 minutes.

22. (Currently Amended) The method of claim 18, wherein the composition comprises: the at least one skin permeation enhancer in an amount from about 1% to about 5% by weight based on the total weight of the composition; and

the at least one active ingredient present in an amount from about 1% by weight to about 10% by weight based on the total weight of the composition;

wherein the composition further comprises:

the at least one effervescent agent present in an amount from about 30% to about 70% by weight based on the total weight of the composition; and

at least one acid agent present in an amount from about 20% to about 40% by weight based on the total weight of the composition;

wherein the at least one skin permeation enhancer and the at least one active ingredient are present in a weight ratio from about 3.0:0.5 to about 0.5:3.0.

23. (Previously Presented) The method of claim 18, wherein the composition is a tablet ranging in size from 10 grams to 400 grams.

24. (Previously Presented) The method of claim 18, wherein the bath comprises a bathtub.

25. (Currently Amended) A method of delivering ibuprofen across the skin comprising treating at least one symptom as a result of transdermal delivery of an active ingredient, wherein the transdermal delivery comprises:

dissolving a composition in form of a tablet in a bath, the composition comprising:

at least one skin permeation enhancer comprising clarified sesame oil in an amount from about 1% to about 5% by weight based on the total weight of the composition; and

at least one active ingredient comprising ibuprofen present in an amount from about 1% by weight to about 10% by weight based on the total weight of the composition;

at least one effervescent agent present in an amount from about 30% to about 70% by weight based on the total weight of the composition; and

at least one acid agent present in an amount from about 20% to about 40% by weight based on the total weight of the composition; and

immersing a body or part of a body in the bath for at least five minutes.

26. (New) The method of claim 19, wherein the skin permeation enhancer further comprises isopropyl myristate.

27. (New) The method of claim 19, wherein
the effervescent agent is sodium bicarbonate; and
the acid agent is citric acid; and
wherein the method is performed at least twice during a 24 hour period.

28. (New) The method of claim 26, wherein
the effervescent agent is sodium bicarbonate; and
the acid agent is citric acid; and
wherein the method is performed at least twice during a 24 hour period.